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510(k) Summary

510(k) Number: K113828

Date Prepared: February 22, 2012

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92.

A. Submitter:

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B. Company Contact:

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Project Manager
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C. Device Information:

Trade Name: *DynaNail Ankle Arthrodesis Nail*
Common Name: Ankle Nail

D. Classification Name: Intramedullary Fixation Rod
HSB 21 CFR 888.3020

E. Predicate Device(s):

DynaNail™ Ankle Nail, Intramedullary Fixation Rod, K101934
DePuy Ace VersaNail™Intramedullary Fixation Rod, K023115

F. Physical Description:

The proposed DynaNail™ is sterile, single use titanium Intramedullary Fixation Rod for use in tibiotalocalcaneal fusions. The DynaNail is available in 10, 11, and 12mm diameters and lengths of 180mm, 220mm, 260mm, and 300mm. The DynaNail is implanted with a deployment frame and fixation screws. The fixation screws are single use 5mm titanium headed and headless screws. The screws are available in lengths that range from 20 to

110mm. Similar to existing IMFR's, the DynaNail™ provides rigid fixation across the arthrodesis site, and also provides a method of in-line compression through the nail. The nail incorporates a method of compression that is applied during implantation in the same fashion as existing nails.

G. Indications for Use:

The DynaNail™ Ankle Nail is intended for tibio-talo-calcaneal fusions:

- Post-traumatic and degenerative arthritis.
- Post-traumatic or primary arthrosis involving both ankle and subtalar joints.
- Revision after failed ankle arthrodesis with subtalar involvement.
- Failed total ankle arthroplasty.
- Non-union ankle arthrodesis.
- Rheumatoid hindfoot.
- Absent Talus (requiring tibiocalcaneal arthrodesis).
- Avascular necrosis of the talus.
- Neuroarthropathy or neuropathic ankle deformity.
- Neuromuscular disease and severe deformity.
- Osteoarthritis.
- Charcot Foot.
- Previously infected arthrosis, second degree

H. Comparison of Technological Characteristics:

The DynaNail is substantially equivalent in design, function and intended use to the following predicate devices:

DynaNail™ Ankle Nail, Intramedullary Fixation Rod, K101934
DePuy Ace VersaNail™ Intramedullary Fixation Rod, K023115

The construction of the DynaNail™ body is equivalent to that of the previously cleared DynaNail™ device as well as the VersaNail™ device. The manufacture and processing of all patient contacting materials are identical to the predicate DynaNail™ K101934. The DynaNail™ device is offered in comparable diameters (10-12mm) and lengths (180-300mm) to the predicate VersaNail™. The DynaNail™ utilizes the same deployment method and external frame technology as the predicate DynaNail™ K101934

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Functional performance analysis of the predicate and proposed DynaNail™ and VersaNail™ were conducted per IM.v4 and ASTM F 1264-03. Analysis substantiates the statement that the proposed device performs equivalently to the predicate devices.

Jeremy Blair
Project Manager

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

MedShape Solutions, Inc.
% Mr. Jeremy Blair
1575 Northside Drive, Suite 440
Atlanta, Georgia 30318

FEB 2 9 2012

Re: K113828
Trade/Device Name: DynaNail Ankle Arthrodesis Nail
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: II
Product Code: HSB
Dated: December 22, 2011
Received: December 28, 2011

Dear Mr. Blair:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K113828

Device Name: DynaNail™ Ankle Arthrodesis Nail

Indications for Use:

The DynaNail™ Ankle Nail is intended for tibio-talo-calcaneal fusions:

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- Osteoarthritis.
- Charcot Foot.
- Previously infected arthrosis, second degree

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K113828